

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

ASSOCIATION FOR ACCESSIBLE
MEDICINES,

Plaintiff,

v.

ROB BONTA, in his official capacity as
Attorney General of the State of California,

Defendant.

No. 2:20-cv-01708-TLN-SCR

ORDER

This matter is before the Court pursuant to Defendant Rob Bonta's, in his official capacity as Attorney General of the State of California ("Defendant" or the "State"), and Plaintiff Association for Accessible Medicines' ("Plaintiff") Motions for Summary Judgment. (ECF Nos. 68, 70.) Both motions are fully briefed.¹ (ECF Nos. 76, 77, 84-2, 85.) For the reasons set forth below, the motions are GRANTED in part and DENIED in part.

///

///

///

///

¹ Portions of the briefing accompanying this motion have been redacted and instead filed under seal at ECF Nos. 73, 75, 80, and 82.

1 **I. FACTUAL AND PROCEDURAL BACKGROUND²**

2 On October 7, 2019, California Governor Gavin Newsom signed Assembly Bill 824 (“AB
3 824”) into law. AB 824 creates a presumption that “reverse payment” settlement agreements
4 regarding patent infringement claims between brand-name and generic pharmaceutical companies
5 are anticompetitive and unlawful.

6 Reverse payment settlement agreements arise primarily — if not exclusively — in the
7 context of pharmaceutical drug regulations and suits brought under the statutory provisions of the
8 Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the
9 Hatch-Waxman Act. Under the Hatch-Waxman Act, once a brand-name company has submitted
10 a new prescription drug to the U.S. Food and Drug Administration (“FDA”) and gained approval
11 to market it, a manufacturer of a generic drug with the same active ingredients that is biologically
12 equivalent to the approved brand-name drug can gain approval to market the generic through an
13 abbreviated FDA process. The New Drug Application (“NDA”) process to which new
14 prescription drugs are subject is long, comprehensive, and expensive, whereas the Abbreviated
15 New Drug Application (“ANDA”) process to which generic drugs are subject is substantially less
16 expensive and requires far less testing.

17 In order to gain approval through the FDA, the generic company must file an ANDA. As
18 part of this application, the generic company must assure the FDA that its drug will not infringe
19 on any patents owned by the brand-name company. One way to do so is for the generic company
20 to certify that any listed, relevant patent is invalid or will not be infringed by the manufacture,
21 use, or sale of the generic drug. This is called Paragraph IV certification. Because filing under
22 Paragraph IV indicates there are current patents the generic company asserts are invalid or
23 un infringed by its product, the Paragraph IV certification is per se a patent infringement and thus
24 the brand-name company can and often does bring suit against the generic drug manufacturer.

25 Settlements of the resulting lawsuits sometimes include reverse payments in which the
26 plaintiff, the brand-name company, pays the defendant, the infringing generic company, a sum of

27 ² The following factual background is taken mostly verbatim from the Court’s December 9,
28 2021, Order granting Plaintiff’s motion for preliminary injunction. (ECF No. 42.)

1 money for the promise that the generic company will keep its drug off the market for an agreed-
2 upon length of time.

3 AB 824 targets these types of settlements. According to the State, AB 824 closes this
4 loophole in the Hatch-Waxman Act and ensures a brand-name company cannot continue to
5 enforce an otherwise weak patent against generic companies through these reverse payment
6 settlement agreements. AB 824 imposes a presumption that a settlement agreement involving a
7 brand-name company compensating the generic company for keeping its drug off the market is
8 anticompetitive under California antitrust law. It also levies a civil penalty against any individual
9 who assists in the violation of the section of three times the value received by the individual due
10 to the violation or \$20 million, whichever is greater.

11 Plaintiff is a nonprofit, voluntary association comprised of the leading manufacturers and
12 distributors of generic and biosimilar medicines, manufacturers and distributors of bulk active
13 pharmaceutical ingredients, and suppliers of other goods and services to the generic and
14 biosimilar pharmaceutical industry. Plaintiff previously filed suit in an attempt to invalidate AB
15 824. (ECF No. 1, No. 2:19-cv-02281-TLN-DB.) In the related case, Plaintiff also filed a motion
16 for preliminary injunction (ECF No. 10, No. 2:19-cv-02281-TLN-DB), which the Court denied
17 (ECF No. 29, No. 2:19-cv-02281-TLN-DB). The Court found, primarily due to the nature of
18 Plaintiff's pre-enforcement attack on AB 824, Plaintiff failed to establish a likelihood of success
19 on the merits or raise serious questions going to the merits. (*Id.*) The Court concluded that
20 absent a constitutional violation, Plaintiff failed to establish an irreparable harm that was both
21 likely and imminent. (*Id.*) Plaintiff subsequently filed an interlocutory appeal of the Court's
22 decision to the Ninth Circuit. (ECF No. 31, No. 2:19-cv-02281-TLN-DB.) The Ninth Circuit
23 heard oral arguments on the matter and ultimately vacated this Court's order and remanded with
24 instructions to dismiss without prejudice, finding Plaintiff failed to demonstrate its members had
25 an Article III injury in fact and concluding Plaintiff lacked associational standing to bring claims
26 on its members' behalf. (*See* ECF Nos. 46–47, No. 2:19-cv-02281-TLN-DB.) The Court
27 subsequently dismissed the suit without prejudice pursuant to the Ninth Circuit's memorandum
28 and mandate. (ECF Nos. 48–49, No. 2:19-cv-02281-TLN-DB.)

1 On August 25, 2020, Plaintiff filed the instant Complaint alleging near-identical causes of
2 action to its prior suit, once again in an attempt to invalidate AB 824: (1) Declaratory/Injunctive
3 Relief — Commerce Clause — Extraterritoriality; (2) Declaratory/Injunctive Relief —
4 Preemption; (3) Declaratory/Injunctive Relief — Excessive Fines Clause; and (4)
5 Declaratory/Injunctive Relief — Due Process — Burden-Shifting. (ECF No. 1 at 21–33.) On
6 December 9, 2021, the Court granted Plaintiff’s motion for a preliminary injunction, finding
7 Plaintiff sufficiently alleged Article III standing and Plaintiff was likely to succeed on the merits
8 of its dormant Commerce Clause claim. (ECF No. 42.)

9 On February 15, 2022, the Court granted the State’s motion in part to modify the
10 preliminary injunction, allowing the State to enforce the provisions of AB 824 with respect to
11 settlement agreements negotiated, completed, or entered into within California’s borders. (ECF
12 No. 47.) The injunction bars the Attorney General of the State of California, as well as the
13 Attorney General’s officers, agents, employees, attorneys, and all persons in active concert or
14 participation with them from implementing or enforcing AB 824 against Plaintiff, its member
15 entities, or their agents and licensees, with the exception of settlement agreements negotiated,
16 completed, or entered into within California’s borders. (*Id.*)

17 On September 15, 2023, the State and Plaintiff filed the instant motions for summary
18 judgment. (ECF Nos. 68, 70.)

19 II. STANDARD OF LAW

20 Summary judgment is appropriate when the moving party demonstrates no genuine issue
21 of any material fact exists and the moving party is entitled to judgment as a matter of law. Fed.
22 R. Civ. P. 56(a); *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970). Under summary
23 judgment practice, the moving party always bears the initial responsibility of informing the
24 district court of the basis of its motion, and identifying those portions of “the pleadings,
25 depositions, answers to interrogatories, and admissions on file together with affidavits, if any,”
26 which it believes demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v.*
27 *Catrett*, 477 U.S. 317, 323 (1986). “[W]here the nonmoving party will bear the burden of proof
28 at trial on a dispositive issue, a summary judgment motion may properly be made in reliance

1 solely on the pleadings, depositions, answers to interrogatories, and admissions on file.” *Id.* at
2 324 (internal quotation marks omitted). Indeed, summary judgment should be entered against a
3 party who does not make a showing sufficient to establish the existence of an element essential to
4 that party’s case, and on which that party will bear the burden of proof at trial. *Id.* at 322.

5 If the moving party meets its initial responsibility, the burden then shifts to the opposing
6 party to establish that a genuine issue as to any material fact does exist. *Matsushita Elec. Indus.*
7 *Co. v. Zenith Radio Corp.*, 475 U.S. 574, 585–87 (1986); *First Nat’l Bank of Ariz. v. Cities Serv.*
8 *Co.*, 391 U.S. 253, 288–89 (1968). In attempting to establish the existence of this factual dispute,
9 the opposing party may not rely upon the denials of its pleadings, but is required to tender
10 evidence of specific facts in the form of affidavits, and/or admissible discovery material, in
11 support of its contention that the dispute exists. Fed. R. Civ. P. 56(c). The opposing party must
12 demonstrate that the fact in contention is material, *i.e.*, a fact that might affect the outcome of the
13 suit under the governing law, *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986), and that
14 the dispute is genuine, *i.e.*, the evidence is such that a reasonable jury could return a verdict for
15 the nonmoving party. *Id.* at 251–52.

16 In the endeavor to establish the existence of a factual dispute, the opposing party need not
17 establish a material issue of fact conclusively in its favor. *First Nat’l Bank*, 391 U.S. at 288–89.
18 It is sufficient that “the claimed factual dispute be shown to require a jury or judge to resolve the
19 parties’ differing versions of the truth at trial.” *Id.* Thus, the “purpose of summary judgment is to
20 ‘pierce the pleadings and to assess the proof in order to see whether there is a genuine need for
21 trial.’” *Matsushita*, 475 U.S. at 587 (quoting Rule 56(e) advisory committee’s note on 1963
22 amendments).

23 In resolving the summary judgment motion, the court examines the pleadings, depositions,
24 answers to interrogatories, and admissions on file, together with any applicable affidavits. Fed.
25 R. Civ. P. 56(c); *SEC v. Seaboard Corp.*, 677 F.2d 1301, 1305–06 (9th Cir. 1982). The evidence
26 of the opposing party is to be believed, and all reasonable inferences that may be drawn from the
27 facts pleaded before the court must be drawn in favor of the opposing party. *Anderson*, 477 U.S.
28 at 255. Nevertheless, inferences are not drawn out of the air, and it is the opposing party's

obligation to produce a factual predicate from which the inference may be drawn. *Richards v. Nielsen Freight Lines*, 602 F. Supp. 1224, 1244–45 (E.D. Cal. 1985), *aff'd*, 810 F.2d 898 (9th Cir. 1987). Finally, to demonstrate a genuine issue that necessitates a jury trial, the opposing party “must do more than simply show that there is some metaphysical doubt as to the material facts.” *Matsushita*, 475 U.S. at 586. “Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no ‘genuine issue for trial.’” *Id.* at 587.

III. ANALYSIS

The State argues the participation of each of Plaintiff’s members is necessary to establish associational standing and all of Plaintiff’s claims fail on the merits. (ECF No. 68-1 at 11–25.) Plaintiff argues there are no genuine disputes of fact regarding its standing and that it succeeds on the merits of its dormant Commerce Clause claim.³ (ECF No. 70 at 6–13.) The Court will first address standing and then address each of the claims in turn.

A. Standing⁴

“[A]n association has standing to bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization’s purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.” *Hunt v. Wash. State*

³ Plaintiff also asserts in a footnote that it disagrees with the Court’s resolution of its other claim and “as a formal matter, ask the Court to enter judgment on all of [its] claims.” (ECF No. 70 at 11 fn. 2.) Because Plaintiff does not develop any new substantive arguments with respect to the remaining claims in its own briefing, the Court will cite to the briefing in the State’s motion for the remaining claims. The Court will cite to the briefing in both motions for Plaintiff’s dormant Commerce Clause claim.

⁴ Plaintiff argues the State waived its associational standing argument by failing to raise it sooner. (ECF No. 77 at 9–11.) Because the Court finds that Plaintiff has established associational standing, the Court declines to consider this argument.

Additionally, in Plaintiff’s motion for summary judgment, Plaintiff preemptively asserts that there are no genuine disputes of fact regarding Article III standing. (*See* ECF No. 70 at 6–11.) In its opposition, the State does not challenge Article III standing but contends Plaintiff does not have associational standing. (ECF No. 76 at 11–12.) Plaintiff and the State make identical and overlapping arguments regarding associational standing in the briefing for both motions. Accordingly, because the State is directly challenging associational standing, the Court will cite to the State’s motion in this section.

1 *Apple Advertising Com’n*, 43 U.S. 333, 343 (1977). Because the parties only dispute whether
 2 Plaintiff meets the third prong of this test, the Court declines to address the first and second
 3 prongs.

4 The State argues that because the preliminary injunction does not enjoin settlements that
 5 are negotiated, completed, or entered into within California’s borders, an individualized inquiry is
 6 required to determine whether a particular settlement fits within this category — namely, whether
 7 the Plaintiff member and its counterparty are based in California. (ECF No. 73 at 12 (under
 8 seal).) The State notes that two of Plaintiff’s members have been engaged in litigation with a
 9 company that has its principal place of business in California, suggesting that the members are
 10 not entitled to injunctive relief at least as to settlements with this company.⁵ (*Id.* (citing ECF No.
 11 73-2 at 9–49; ECF No. 73-3 at 24–285).) The State also notes that at least two of Plaintiff’s
 12 members — Antheia, Inc. and Amphastar Pharmaceuticals, Inc. — have their principal places of
 13 business in California. (*Id.*) The State argues, therefore, individualized inquiries are necessary to
 14 determine entitlement to Plaintiff’s requested remedy, which preclude associational standing.
 15 (ECF No. 68-1 at 12–13.)

16 Plaintiff maintains that “[i]ndividualized proof from the members is not needed where, as
 17 here, declaratory and injunctive relief is sought rather than monetary damages.” (ECF No. 77 at
 18 11–12 (citing *Associated Gen. Contractors of Am. v. Metro. Water Dist. of S. Cal.*, 159 F.3d
 19 1178, 1181 (9th Cir. 1998)).) Plaintiff asserts that associational standing is not defeated when
 20 some members would not have standing on their own and *Hunt*’s test allows the case to move
 21 forward even if not all the members have standing to sue. (*Id.* at 12.) Plaintiff notes the State’s
 22 contention that some members will be unable to enforce the injunction against the State does not
 23 change the fact that the Court can grant (and has already granted) Plaintiff’s requested relief
 24 without members’ participation. (*Id.*) Plaintiff argues it is black-letter law that *Hunt*’s third

25 ⁵ In support of its argument, Plaintiff submits a Request for Judicial Notice seeking to
 26 judicially notice Exhibit C, a Plaintiff’s member’s Complaint filed in ongoing litigation. (ECF
 27 No. 73-3 at 1–3, 24–285.) The Court “may take judicial notice of court filings and other matters
 28 of public record.” *Reyn’s Pasta Bella, LLC v. Visa USA, Inc.*, 442 F.3d 741, 746, n.6 (9th Cir.
 2006). Because Exhibit C is a court filing, Plaintiff’s request with respect to Exhibit C is
 GRANTED.

1 prong is satisfied when an association seeks uniform injunctive relief and its claim “raises a pure
 2 question of law” that can be decided without reference to any particular facts. (*Id.* at 13 (citing
 3 *Int’l Union, United Auto., Aerospace and Agric. Implement Workers of Am. v. Brock* (UAW), 477
 4 U.S. 274, 287–88 (1986).) Plaintiff maintains that while its claim is as-applied in that it only
 5 seeks to strike AB 824 to the extent it applies to settlements completed wholly out of state, it also
 6 contends the claim is facial because it challenges application of AB 824 more broadly to all
 7 settlements completed wholly out of state. (*Id.* at 13 n.3.)

8 The third prong in *Hunt*’s associational standing test “is best seen as focusing on these
 9 matters of administrative convenience and efficiency, not on elements of a case or controversy
 10 within the meaning of the Constitution.” *United Food & Com. Workers Union Local 751 v.*
 11 *Brown Grp., Inc.*, 517 U.S. 544, 557 (1996). Accordingly, while the first two prongs of the
 12 associational standing inquiry are constitutional, the third prong is prudential. *Oregon Advocacy*
 13 *Ctr. v. Mink*, 322 F.3d 1101, 1109 (9th Cir. 2003). The third prong considers whether “there is
 14 complete identity between the interests of the consortium and those of its member[s] . . . and the
 15 necessary proof could be presented ‘in a group context.’” *N.Y. State Club Ass’n, Inc. v. City of*
 16 *New York*, 487 U.S. 1, 10 n.4 (1988) (citing *Hunt*, 432 U.S. at 344). It also considers whether the
 17 “challenge raises a pure question of law that is not specific to individual members.” *Ass’n of*
 18 *Christian Sch. Int’l v. Stearns* (*Stearns*), 678 F. Supp. 2d 980, 985 (C.D. Cal. 2008), *aff’d*, 362 F.
 19 App’x 640 (9th Cir. 2010). An organization does not have associational standing when its claims
 20 “require an ‘ad hoc factual inquiry’ for each member represented by the association.” *City of S.*
 21 *Lake Tahoe Retirees Ass’n v. City of S. Lake Tahoe* (*S. Lake Tahoe Retirees Ass’n*), No. 2:15-cv-
 22 02502-KJM-CKD, 2017 WL 2779013, at *3 (E.D. Cal June 27, 2017) (citing *Stearns*, 678 F.
 23 Supp. 3d at 986; *Rent Stabilization Ass’n of City of N.Y. v. Dinkins* (*Dinkins*), 5 F.3d 591, 596 (2d
 24 Cir. 1993)).

25 Both the Supreme Court and Ninth Circuit have recognized associational standing where
 26 associations sought declaratory and injunctive relief and not where associations sought monetary
 27 damages. See *S. Lake Tahoe Retirees Ass’n*, 2017 WL 2779013, at *3 (citing cases). However,
 28 courts have generally held that associations lack standing to bring as-applied constitutional

1 challenges, regardless of the relief sought, because the as-applied claims would have required
 2 individualized factual inquiries for each member of the association. *Stearns*, 678 F. Supp. 2d at
 3 985–86 (finding plaintiffs’ as-applied claims and the relief they sought, though equitable in
 4 nature, both required “‘individualized proof’ specific to each rejected course and the school that
 5 offered it”); *Dinkins*, 5 F.3d at 592–93 (finding no associational standing for as-applied claims
 6 because the court would have had to “engage in an *ad hoc* factual inquiry for *each* [member] who
 7 allege[d] that he ha[d] suffered a taking,” in addition to other individualized inquiries (emphasis
 8 in original)). Nevertheless, courts have recognized in certain circumstances that associations can
 9 bring as-applied challenges. *See Ne. Fla. Chapter of the Associated Gen. Contractors v. City of*
 10 *Jacksonville*, 508 U.S. 656 (1993) (finding an association of contractors challenged as a violation
 11 of the Equal Protection Clause a Jacksonville ordinance requiring ten percent of the amount spent
 12 on city contracts to be set aside for minority business enterprises (“MBEs”) and whether non-
 13 MBEs “had been denied equal protection depended on a purely legal analysis of the ordinance
 14 and of the law of Equal Protection”).⁶

15 Here, Plaintiff seeks only declaratory and injunctive relief with respect to all its claims.
 16 (ECF No. 1 at 21–34.) Specifically, Plaintiff states in its Complaint that it prays for: “a
 17 declaration, pursuant to 28 U.S.C. § 2201, that AB 824 violates the United States Constitution
 18 and is therefore void and unenforceable;” “a preliminary injunction prohibiting the Attorney
 19 General from implementing and enforcing AB 824;” and “a permanent injunction prohibiting the
 20 Attorney General from implementing and enforcing AB 824[.]” (*Id.* at 33–34.) The Court has
 21 held previously that Plaintiff’s claim is as-applied as it “does not seek to strike [AB 824] in all its
 22 applications, but only to the extent it applies to settlements completed wholly out of state.” (ECF
 23 No. 77 at 13 n.3 (internal citation and quotations omitted); ECF No. 47 at 14.) Further, as
 24 Plaintiff notes, the Supreme Court held in *John Doe v. Reed*, 561 U.S. 186, 194 (2010), that a
 25 challenge is also facial when it “challenges application of the law more broadly.” (ECF No. 77 at

26 ⁶ The challenge in *City of Jacksonville* was both facial and as-applied. Admittedly, while
 27 there was no challenge regarding associational standing, the Supreme Court stated that “given the
 28 current state of the record, [it had no] basis for” concluding that “one or more of the prerequisites
 to ‘associational standing’ have not been satisfied.” 508 U.S. at 669 n.6.

1 13 n.3.) Plaintiff’s challenge is therefore also facial, in that it is not limited to a particular
2 settlement but “challenges the application of the law more broadly” to all settlements completed
3 wholly out of state. (*Id.*)

4 While the State is correct that Plaintiff and its members are not entitled to injunctive relief
5 with respect to settlements negotiated, completed, or entered into within California’s borders
6 (ECF No. 68-1 at 12), what Plaintiff seeks is an injunction striking AB 824 only to the extent that
7 it applies to settlements completed wholly out of state. Plaintiff is not seeking monetary
8 damages, the amounts of which could vary from member to member, nor is it challenging the
9 application of AB 824 to specific patent settlement agreements. (ECF No. 77 at 12.) Further,
10 even if Plaintiff’s requested remedy required *some* individual participation by inquiring into
11 whether a settlement agreement was completed wholly outside of California, the State “has not
12 explained how the potential for some individual participation threatens administrative
13 convenience or efficiency.” *S. Lake Tahoe Retirees Ass’n*, 2017 WL 2779013, at *4. Plaintiff’s
14 claims “involve questions that apply to all members and are well-suited to association-level
15 resolution.” *Id.* Accordingly, even though *some* individual member participation may be
16 necessary to determine whether a settlement agreement was completed wholly outside of
17 California, “that potential does not preclude standing under *Hunt*.” *Id.* (citing cases).

18 The Court also finds the cases to which the State cites are distinguishable from the instant
19 matter because the remedies sought would have required more than just *some* individualized
20 factual inquiries — the inquiries would have been extensive. *See Kansas Health Care Ass’n v.*
21 *Kansas Dep’t of Social and Rehabilitation Servs.*, 958 F.2d 1018, 1022–23 (10th Cir. 1992)
22 (finding association lacked standing to challenge Medicaid reimbursement rates set by state
23 department because proof and resolution of the claims would have required examination of
24 evidence of reimbursement rates particular to individual providers); *Dinkins*, 5 F.3d at 597
25 (finding no associational standing where the court would have to engage in an *ad hoc* factual
26 inquiry for each landlord who alleged he suffered a taking, which would have included “the
27 landlord’s particular return based on a host of individualized financial data” and investigation of
28 “the reasons for any failure to obtain an adequate return”); *Stearns*, 678 F. Supp. 2d at 985–86

(finding plaintiffs’ as-applied claims and the relief they sought, though equitable in nature, both required “‘individualized proof’ specific to each rejected course and the school that offered it and plaintiffs did not rebut defendants’ assertion that they seek an order requiring defendants to reconsider (or approve) specific proposed courses).

Based on the foregoing, Plaintiff has sufficiently established the third prong in *Hunt* — that “neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.” 43 U.S. at 343. Accordingly, the Court finds that Plaintiff has associational standing to bring its claims in the instant matter.

B. Dormant Commerce Clause (Claim One)

In its first claim, Plaintiff alleges “AB 824 violates the Commerce Clause as applied to settlement agreements that were not negotiated, completed, or entered in California.” (ECF No. 1 at 23.)

The Commerce Clause provides that “Congress shall have power . . . [t]o regulate Commerce . . . among the several States.” U.S. Const., art. I, § 8, cl. 3. “This affirmative grant of power does not explicitly control the several states, but it ‘has long been understood to have a “negative” aspect that denies the States the power unjustifiably to discriminate against or burden the interstate flow of articles of commerce.’” *Rocky Mountain Farmers Union v. Corey* (*Rocky Mountain*), 730 F.3d 1070, 1087 (9th Cir. 2013) (quoting *Or. Waste Sys., Inc. v. Dep’t of Env’tl Quality of State of Or.*, 511 U.S. 93, 98 (1994)); *Wyoming v. Oklahoma*, 502 U.S. 437, 454 (1992)). The “negative” or “dormant” Commerce Clause “prohibits discrimination against interstate commerce and bars state regulations that unduly burden interstate commerce.” *Id.*; *Sam Francis Found. v. Christies, Inc.* (*Sam Francis*), 784 F.3d 1320, 1323 (9th Cir. 2015) (internal citation omitted). The Supreme Court has articulated a two-tiered approach to evaluate state economic regulation under the Commerce Clause: “[1] When a state statute directly regulates or discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out-of-state interests, [the Court has] generally struck down the statute without further inquiry. [2] When, however, a statute only has indirect effects on interstate commerce and regulates evenhandedly, [the Court has] examined whether the State’s interest is legitimate and

1 whether the burden on interstate commerce clearly exceeds the local benefits.” *Ass’n des*
2 *Eleveurs de Canards et d’Oies du Quebec v. Harris*, 729 F.3d 937, 948 (9th Cir. 2013) (quoting
3 *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth. (Brown-Forman)*, 476 U.S. 573, 578–
4 79 (1986)).

5 With respect to direct regulation of interstate commerce occurring wholly outside of a
6 state’s borders, also known as the extraterritoriality doctrine, the dormant Commerce Clause
7 provides that “any ‘statute that directly controls commerce occurring wholly outside the
8 boundaries of a State exceeds the inherent limits of the enacting State’s authority.’” *Rocky*
9 *Mountain*, 730 F.3d at 1101 (quoting *Healy v. Beer Instit.*, 49 U.S. 324, 336 (1989)). The critical
10 inquiry “is whether the practical effect of the regulation is to control conduct beyond the
11 boundary of the state.” *Id.* (quoting *Healy*, 49 U.S. at 336; *Brown-Forman*, 476 U.S. at 579). To
12 determine the practical effect, the Ninth Circuit considers the direct consequences of the statute as
13 well as “how the challenged statute may interact with the legitimate regulatory regimes of other
14 States and what effect would arise if not one, but many or every, State adopted similar
15 legislation.” *Id.*

16 The State argues the Supreme Court’s decision in *National Pork Producers Council v.*
17 *Ross (Pork Producers)*, 598 U.S. 356 (2023), precludes Plaintiff’s sole dormant Commerce
18 Clause argument, which is that any regulation affecting commerce beyond California’s borders is
19 unconstitutional “without exception.” (ECF No. 68-1 at 13–14.) The State contends Plaintiff
20 relies on the *Healy-Baldwin* line of cases to argue for the application of a “per se”
21 extraterritoriality doctrine, but the Supreme Court rejected this argument in *Pork Producers* and
22 “held there is no such prohibition on extraterritorial regulation.” (*Id.* (citing *Pork Producers*, 598
23 U.S. at 371).) The State further contends Plaintiff cannot succeed under the clarified
24 understanding of the *Healy-Baldwin* line of cases because AB 824 is not a price control or price
25 affirmation statute. (*Id.* at 15.) The State finally argues that AB 824 only applies to settlements
26 that cover drug sales in California and Plaintiff’s argument runs counter to common law
27 regarding application of state antitrust statutes. (*Id.* at 15–21.)

28 ///

Plaintiff argues *Pork Producers* does not change the law relevant to Plaintiff's extraterritoriality claim — AB 824 directly regulates settlements “even if the[y] w[ere] completed entirely out of state, resolved an out-of-state case, and w[ere] between two out-of-state companies, and even if neither party to the settlement sells its products directly into California, but rather sells only to national wholesalers and delivers their products outside of California.” (ECF No. 70 at 11 (citing ECF No. 1 ¶ 82).) Unlike the instant case, Plaintiff notes *Pork Producers* did not involve a direct regulation on out-of-state commerce claim, but rather a claim that the California law at issue had indirect “practical effects” on out-of-state commerce which were too great. (*Id.* at 12.) Plaintiff maintains that binding precedent “doom[s]” AB 824 because it directly regulates out-of-state transactions, which this Court has already recognized. (*Id.* at 12–13 (citing *Sam Francis*, 784 F.3d at 1323–25; *Daniels Sharpsmart v. Smith (Sharpsmart)*, 889 F.3d 608, 615–16 (9th Cir. 2018)).)

The parties' arguments can be distilled into the following questions: (1) whether AB 824 violates the dormant Commerce Clause; (2) whether AB 824 applies only to settlements covering drug sales in California; and (3) whether historical antitrust case law supports upholding AB 824. The Court will address these arguments in turn.

i. Whether AB 824 Violates the Dormant Commerce Clause

As stated previously, both parties contend that *Pork Producers* supports their arguments about the constitutionality of AB 824. The Court will first examine *Pork Producers*, then evaluate its applicability to the instant matter, and dispense with the parties' remaining arguments.

In *Pork Producers*, two organizations representing pork producers filed suit against California officials challenging Proposition 12, which “forbids the in-state sale of whole pork meat that comes from breeding pigs (or their immediate offspring) that are ‘confined in a cruel manner.’” 598 U.S. 356 at 365–66 (citing Cal. Health & Safety Code § 25990(b)(2)). The petitioners argued the dormant Commerce Clause case law — namely, the *Baldwin-Healey* line of cases — suggested an almost “per se” rule that forbids “enforcement of state laws that have the practical effect of controlling commerce outside of the State, even when those laws do not

purposely discriminate against out-of-state interests.” *Id.* at 371. By way of brief summary of these cases, *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935) involved New York laws that barred out-of-state dairy farmers to sell their milk in state “unless the price paid to” them matched the minimum price state law guaranteed in-state farmers. *Id.* at 371–72. The Supreme Court noted the issue was that the laws discriminated against out-of-state farmers by “creating an economic barrier protecting a major local industry against competition from without the State.” *Id.* at 372 (citation omitted). *Brown-Forman*, 476 U.S. 573 and *Healy*, 491 U.S. 324 involved price-affirmation statutes (rather than the price-fixing statute in *Baldwin*). *Id.* The laws at issue in those cases required merchants to affirm their in-state prices were not higher than out-of-state prices and the Supreme Court found in both that they amounted to economic protectionism. *Id.* at 372–73. According to petitioners in *Pork Producers*, Proposition 12 offended a “per se” rule established by these cases by imposing “substantial new costs on out-of-state pork producers who wish to sell their products in California.” *Id.* (internal quotation marks and citations omitted). The Supreme Court ultimately rejected petitioners’ argument, noting that each of the cases they cited for this “per se” rule instead “typifies the familiar concern with preventing purposeful discrimination against out-of-state interests.” *Id.* at 371–72.

Petitioners in *Pork Producers* also pointed to *Edgar v. MITE Corp.*, 457 U.S. 624 (1982) as authority for this “per se” rule. *Id.* at 376 n.1. A plurality in *Edgar* “declined to enforce an Illinois securities law that ‘directly regulate[d] transactions which [took] place . . . wholly outside the State’ and involved individuals ‘having no connection with Illinois.’” *Id.* (emphasis in original). The Supreme Court clarified that the plurality opinion in *Edgar* does not support the rule petitioners propose and instead “spoke to a law that *directly* regulated out-of-state transactions by those with *no* connection to the State.” *Id.* (emphasis in original). As the Court will explain further below, AB 824 is unlike *Pork Producers* as the law can directly regulate out-of-state transactions by those with no connection to California.⁷

⁷ As an initial matter, the Court disagrees with the State’s contention that Plaintiff pivoted to a direct regulation claim in light of *Pork Producers*. (ECF No. 76 at 13.) Plaintiff is correct that its claim “has always been that California lacks constitutional authority to enforce AB 824 vis-à-vis settlements completed out of [S]tate,” and the Court has even previously recognized this

1 The State contends AB 824 “does not offend the direct-regulation principle” and is
 2 “materially indistinguishable” from Proposition 12 in *Pork Producers* as AB 824 “addresses only
 3 out-of-state conduct with in-state impacts.” (ECF No. 76 at 13–14.) The Court finds *Ass’n for*
 4 *Accessible Medicines v. Ellison*, 704 F. Supp. 3d 947 (D. Minn. 2023) instructive. In that case, a
 5 district court in Minnesota enjoined a state law regulating the price of generic and off-patent
 6 prescription drugs⁸ as applied to out-of-state transactions and rejected Minnesota’s attempt to
 7 expand the Supreme Court’s decision in *Pork Producers*. *Ass’n for Accessible Medicines v.*
 8 *Ellison* (*Ellison*), 704 F. Supp. 3d 947 (D. Minn. 2023). The district court clearly noted the
 9 difference between Proposition 12 and the Minnesota law at issue: “The crucial difference,
 10 however, is that [Proposition 12] does not attempt to impose liability on out-of-state actors for
 11 engaging in out-of-state conduct; instead, it regulates in-state actors who engage in in-state
 12 conduct (specifically, in-state sales of meat that has been produced a certain way).” *Id.* Relevant
 13 here, this Court has already found AB 824 may reach a settlement agreement in which none of the
 14 parties, the agreement, or the pharmaceutical sales have any connection with California. (ECF
 15 No. 42 at 15.) **This is fundamentally different from Proposition 12, which only regulates**
 16 **actors engaging in conduct in California. *Ellison*, 704 F. Supp. 3d at 947.**

17 Plaintiff contends binding precedents such as *Sam Francis* and *Sharpsmart* “doom” AB
 18 824 because the law directly regulates out-of-state transactions. (ECF No. 70 at 12.) The State
 19 asserts the Supreme Court curtailed the *Baldwin-Healy* line of cases in *Pork Producers* and that
 20 *Sam Francis* and *Sharpsmart* may no longer be good law because they “relied significantly on the
 21 *Baldwin-Healy* line of cases to reach their respective results.” (ECF No. 76 at 13, 15.) The Court
 22 _____
 23 in its February 15, 2022, Order modifying the preliminary injunction. (ECF No. 85 at 7 (citing
 ECF No. 47 at 5).)

24 ⁸ Specifically, the Minnesota law provides as follows: “No manufacturer shall impose, or
 25 cause to be imposed, an excessive price increase, whether directly or through a wholesale
 26 distributor, pharmacy, or similar intermediary, on the sale of any generic or off-patent drug sold,
 27 dispensed, or delivered to any consumer in the state.” *Ass’n for Accessible Medicines v. Ellison*,
 704 F. Supp. 3d 947, 951 (D. Minn. 2023). In considering plaintiff’s motion for preliminary
 28 injunction, the district court found that plaintiff was likely to succeed on the merits of its dormant
 Commerce Clause claim because the law “directly regulates transactions that take place wholly
 outside of Minnesota.” *Id.* at 953–57.

disagrees. The Supreme Court did not curtail the *Baldwin-Healy* line of cases but only clarified there is no “per se” rule that follows from them. In so doing, the Supreme Court noted “each [of these cases] typifies the familiar concern with preventing purposeful discrimination against out-of-state economic interests.” *Pork Producers*, 598 U.S. at 371.

In light of this, the Court follows the precedent set in *Sam Francis* and *Sharpsmart*. The Ninth Circuit found in *Sam Francis* that California’s Resale Royalty Act’s clause regulating sales outside of California was facially violative of the dormant Commerce Clause because it “facially regulates a commercial transaction that ‘takes place wholly outside the State’s borders.’” 784 F.3d at 1322–24. The language of the clause at issue required the payment of royalties to the artist after the sale of fine art whenever the seller resided in California or the sale took place in California.⁹ *Id.* In *Sharpsmart*, the Ninth Circuit affirmed the district court’s grant of a preliminary injunction, enjoining California Department of Public Health (“Department”) officials from enforcing the California Medical Waste Management Act (“MWMA”). 889 F.3d at 609. Under the MWMA, “California-generated medical waste must be incinerated” and “[m]edical waste transported out of state shall be consigned to a permitted medical waste treatment facility in the receiving state.” *Id.* at 612. The Ninth Circuit found this case “is little different from *Sam Francis*,” as “California has attempted to regulate waste treatment everywhere in the country, just as it tried to regulate art sales.” *Id.* at 616. Therefore, plaintiff was likely to succeed on the merits of its claim that Department officials’ application of the MWMA constituted a “per se violation of the Commerce Clause.” *Id.* Similar to the extraterritorial regulation of art sales and waste treatment, here, AB 824 on its face may result in the extraterritorial regulation of settlement agreements in which none of the parties, the agreement, or the pharmaceutical sales have any connection with California.

///

⁹ The court provided the following example: “if a California resident has a part-time apartment in New York, buys a sculpture in New York from a North Dakota artist to furnish her apartment, and later sells the sculpture to a friend in New York, the Act requires the payment of a royalty to the North Dakota artist — even if the sculpture, the artist, and the buyer never traveled to, or had any connection with, California.” *Id.*

1 The State argues in the alternative that even if *Sam Francis* and *Sharpsmart* remain good
 2 law, the Ninth Circuit has held as long as a State’s ties to the subject of regulation “are
 3 ‘sufficiently strong to justify its assertion of regulatory authority,’ there is no violation of the
 4 principle applied in *Sam Francis* and *Sharpsmart*.” (ECF No. 76 at 15 (citing *Ward v. United*
 5 *Airlines, Inc.*, 986 F.3d 1234, 1240 (9th Cir. 2021)).) Specifically, the State argues that “the
 6 Ninth Circuit invalidated laws that it held had no in-state effects that would establish a
 7 sufficiently strong ‘tie’ between the State and the underlying subject of regulation.” (*Id.* at 17.)
 8 This argument is unpersuasive. The Ninth Circuit did not invalidate the laws in *Sam Francis* and
 9 *Sharpsmart* on this basis. To the contrary, despite the State having sufficiently strong ties to the
 10 subjects of regulation (namely, attempting to regulate state residents’ conduct), the Ninth Circuit
 11 struck down the statutes because they allowed the State to regulate conduct or transactions that
 12 had no connection to or any effect in California. *Sam Francis*, 784 F.3d at 1322–24; *Sharpsmart*,
 13 889 F.3d at 613.

14 Finally, the State contends the “true ‘direct regulation’ cases” the Supreme Court cites
 15 “are easily distinguishable because those cases involved laws with no (or virtually no) connection
 16 with the regulating state, thereby making their ties to the subject of regulation too weak to
 17 withstand constitutional scrutiny.”¹⁰ (ECF No. 76 at 16 (citing *Edgar*, 457 U.S. 624 (1982))). As
 18 previously stated, a plurality in *Edgar* found an Illinois law — that required a tender offeror to
 19 notify the Secretary of State and the target company of its intent to make a tender offer and the

20
 21 ¹⁰ The State also cites to *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797 (1985) as one of
 22 these “true ‘direct regulation’ cases.” (ECF No. 76 at 16.) However, as the State admits, *Shutts*
 23 involves application of the Due Process Clause to a Kansas law and does not engage in any
 analysis about the Commerce Clause. *Shutts* is therefore not a “direct regulation” case and the
 Court declines to consider it.

24 The Court also notes the State’s citation to *Ward* for this principle does not change its
 25 analysis. The Ninth Circuit held the California statute in *Ward* regulating wage statements
 26 provided to pilots and flight attendants whose principal place of work was in California did not
 27 violate the dormant Commerce Clause because what the statute regulates is “the employment
 28 relationship between employer and employee,” and the plaintiffs were all “based for work
 purposes in California and perform at least some work in California.” 986 F.3d at 1240–41.
 Therefore, the conduct the California statute regulates was not wholly or even mostly occurring
 outside the State.

1 material terms of the offer twenty business days before the offer becomes effective — to be “a
 2 direct restraint on interstate commerce.” 457 U.S. at 634–35, 642. The plurality concluded the
 3 law, unless complied with, sought to prevent defendant from making its offer and concluding
 4 interstate transactions not only with the target company’s stockholders living in Illinois but also
 5 with those living in other States with no connection to Illinois. *Id.* at 642. The law on its face
 6 would apply even if not one of the target company’s shareholders was a resident of Illinois, since
 7 it applied to “every tender offer for a corporation meeting two of the following conditions: the
 8 corporation has its principal executive office in Illinois, is organized under Illinois laws, or has at
 9 least 10% of its stated capital and paid-in surplus represented in Illinois.” *Id.* The plurality
 10 opinion did not invalidate the Illinois law on the basis that it involved “no (or virtually no)
 11 connection with the regulating state.” Rather, despite a clear connection with Illinois —
 12 regulating Illinois-based companies’ conduct — the Supreme Court struck down the law as an
 13 impermissible restraint on interstate commerce.

14 In sum, the Supreme Court’s decision in *Pork Producers* does not change the Court’s
 15 initial analysis accompanying its December 9, 2021, Order granting Plaintiff’s motion for
 16 preliminary injunction. (ECF No. 42 at 11–15.) The Court therefore need not repeat the same
 17 analysis here. Accordingly, the Court finds AB 824 violates the dormant Commerce Clause to
 18 the extent it regulates settlement agreements in which none of the parties, the agreement, or the
 19 pharmaceutical sales have any connection with California.

20 *ii. Whether AB 824 Applies Only to Settlements Covering Drug Sales*
 21 *in California*

22 The State argues the Court should apply California canons of statutory interpretation and
 23 construe AB 824 as applying only to “‘agreement[s], resolving or settling . . . patent infringement
 24 claim[s], in connection with the sale of a pharmaceutical product’ in California, and not to
 25 settlement agreements with zero connection to California.” (ECF No. 68-1 at 15–19 (citing ECF
 26 No. 42 at 13) (emphasis in original).) Plaintiff maintains the Court has already rejected this
 27 argument. (ECF No. 77 at 17.) Plaintiff asserts in the alternative that even if the Court reversed
 28 itself on this point, the State explicitly concedes AB 824 would still “extend to agreements

1 entered into out-of-state to the extent that they cover California-based sales,” meaning AB 824
 2 directly regulates transactions that occur entirely out of state. (*Id.* at 18 (citing ECF No. 68-1 at
 3 12 n.5).)

4 Here, the Court has already explained in its prior December 9, 2021, Order that AB 824
 5 on its face does not include a limitation to California sales. (ECF No. 42 at 14 n.6); 2019 Cal.
 6 Legis. Serv. 531; *see also Smallwood v. Allied Van Lines, Inc.*, 660 F.3d 1115, 1121 (9th Cir.
 7 2011) (For purposes of statutory interpretation, “[u]nder the ‘plain meaning’ rule, ‘[w]here the
 8 language [of a statute] is plain and admits of no more than one meaning[,] the duty of
 9 interpretation does not arise, and the rules which are to aid doubtful meanings need no
 10 discussion.” (citing *Carson Harbor Vill., Ltd. v. Unocal Corp.*, 270 F.3d 863, 878 (9th Cir. 2001)
 11 (en banc))). The Court therefore cannot read “California sales” into the statute where it was not
 12 written by the State Legislature. Accordingly, AB 824 on its face remains violative of the
 13 dormant Commerce Clause.

14 *iii. AB 824 and State Antitrust Statutes*

15 The State argues Plaintiff’s “dormant Commerce Clause challenge also runs contrary to
 16 the long history and tradition of states regulating antitrust and unfair competition,” as “[f]or over a
 17 century, states have protected their residents from the types of business practices that AB 824
 18 prohibits, even if the misconduct has an incidental impact on interstate commerce or aspects of
 19 the misconduct occur in other States.” (ECF No. 68-1 at 19.) Plaintiff asserts that state antitrust
 20 law is not exempt from the Constitution and “[w]hile state ‘antitrust and unfair competition
 21 statutes’ may constitutionally be applied to conduct that takes place at least partially in
 22 state, . . . state law ‘cannot regulate [transactions] that take place wholly outside it.’” (ECF No.
 23 77 at 20.)

24 The State does not have the authority to enact and enforce antitrust legislation that
 25 otherwise has been found to violate the dormant Commerce Clause. Most importantly, none of
 26 the case law to which the State cites stands for the principle that the State may still enact or
 27 enforce antitrust legislation even if it is found to violate the dormant Commerce Clause. (*See*
 28 ECF No. 68-1 at 19–21.)

Based on the foregoing, the Court finds AB 824 violates the dormant Commerce Clause, except for settlement agreements negotiated, completed, or entered into within California's borders. Accordingly, with respect to Claim One, Plaintiff's motion for summary judgment is GRANTED and the State's motion for summary judgment is DENIED.

C. Preemption (Claim Two), Excessive Fines (Claim Three), and Due Process (Claim Four)

The State argues AB 824 is not preempted, noting the Court "previously rejected" Plaintiff's claims that AB 824 is preempted under: (1) federal patent law; (2) the Hatch-Waxman Act; (3) the Supreme Court's decision in *FTC v. Actavis*, 570 U.S. 136 (2013); and (4) the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"). (ECF No. 68-1 at 21–23.) The State also maintains AB 824 does not violate the prohibition on Excessive Fines nor does it violate due process. (*Id.* at 23–25.)

In opposition, Plaintiff asserts that "because the legal merits of th[e]se claims do not turn on any disputed facts, and nothing about the law has changed,"¹¹ it will not repeat arguments this Court has already rejected. (ECF No. 21–27.) Instead, Plaintiff incorporates by reference its arguments set forth accompanying its motion for preliminary injunction. (*Id.*)

Indeed, with respect to Claims Two, Three, and Four, the Court finds Plaintiff raises identical arguments that it has already addressed in its prior Order in the previous case denying Plaintiff's motion for preliminary injunction (*see* ECF No. 29; No. 2:19-cv-02281-TLN-DB) and its February 15, 2022 Order granting in part and denying in part the State's motion to modify the preliminary injunction (*see* ECF No. 47). Accordingly, the State's motion for summary judgment as to Claims Two, Three, and Four is GRANTED and Plaintiff's motion for summary judgment as to these claims is DENIED.

///

///

¹¹ Plaintiff presumably argues that this is true since the filing date of its opposition — November 6, 2023. Plaintiff has not filed any supplemental briefing to suggest the law or the facts of this case have materially changed since November 6, 2023. The Court therefore assumes that nothing about the law or facts of this case have changed to date.

IV. CONCLUSION


For the foregoing reasons, Plaintiff's motion for summary judgment (ECF No. 68) and the State's motion for summary judgment (ECF No. 70) are GRANTED in part and DENIED in part as follows:

1. Plaintiff's motion for summary judgment as to Claim One is GRANTED;
2. The State's motion for summary judgment as to Claim One is DENIED;
3. Plaintiff's motion for summary judgment as to Claims Two, Three, and Four is DENIED;
- and
4. The State's motion for summary judgment as to Claims Two, Three, and Four is GRANTED.

The Court converts the current preliminary injunction into a permanent injunction. The State may enforce the provisions of AB 824 with respect to settlement agreements negotiated, completed, or entered into within California's borders. The injunction bars the Attorney General of the State of California, as well as the Attorney General's officers, agents, employees, attorneys, and all persons in active concert or participation with them from implementing or enforcing AB 824 against Plaintiff, its member entities, or their agents and licensees, with the exception of settlement agreements negotiated, completed, or entered into within California's borders.

The Clerk of the Court is directed to enter judgment in favor of Plaintiff as to Claim One, enter judgment in favor of the State as to Claims Two, Three, and Four, and close the case.

Date: February 12, 2025



TROY L. NUNLEY
CHIEF UNITED STATES DISTRICT JUDGE